No. 94-372

In The

Supreme Court of the United States

October Term, 1994

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

MARGARET WHITECOTTON, ET AL.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF IN OPPOSITION

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BRIEF IN OPPOSITION

Respondent, Margaret (hereinafter "Maggie") Whitecotton, by and through her parents and next friends, Kay and Michael Whitecotton, respectfully prays that this honorable Court deny the request of Donna E. Shalala, the Secretary of Health and Human Services, to review the order and judgment of the United States Court of Appeals for the Federal Circuit, entered on the 15th day of February, 1994 (*rehearing denied*, April 29, 1994), reversing the judgment of the United States Court of Federal Claims.

INTRODUCTION

The government's rendition of the facts in this case is egregiously stilted. The result is a complete misrepresentation of the meaning of the rule articulated below by the court of appeals. The government would have this case to be a "significant aggravation" vaccine case by making the assertion that Maggie Whitecotton had a preexisting disorder, an "organic brain syndrome." In fact the so-called preexisting condition is completely speculative.

The idea of "preexisting condition" under the Vaccine Act goes cheek-to-jowl with the idea of "factors unrelated." But the instant case was a classic case of vaccine injury. The post-vaccine encephalopathy was manifest by multiple seizures within the first half-day, early in the 72-hour "window" which the Vaccine Injury Table adopts from the majority of medical authorities.[1] The contemporaneous diagnosis of Maggie's condition is that the injury is indeed a DPT-induced encephalopathy.

The defense was also "classic" – that is, overly adversarial and legally misdirected.[2] The government

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[1] As noted by the government, the Act directed the Secretary of DHHS to establish the Program "to achieve . . . optimal prevention against adverse reactions to vaccines." (Petitioner's Brief at page 4.) A recent report generated under this thrust of the Act, from the Institutes of Medicine (IOM), accepts a seven-day window of vulnerability to permanent neurological injury. DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis, National Academy Press, 1994

[2] "Respondents have . . . mounted defenses incompatible with a no-fault system of compensation." House Conf. Rep. No. 101-386, 101st Cong., 1st Sess., page 513; *reprinted* 4 USCCAN 3112, 3116 (1989).

sponsored an expert witness who does not even **believe** in DPT vaccine injury. This expert, Dr. Evans, testified that the contemporaneous dianosis of DPT injury in August of 1975 must have been made (paraphrasing) "because back then they **did** believe in it."[3] The expert's opinion relied upon questionable factors – **not** utilized in the special master's reasoning to deny compensation. Dr. Evans also admitted that the seizures and other features of Maggie's illness are not typical for the "organic brain syndrome" he postulated as a "preexisting" condition.

Dr. Evans testified that Maggie's growth chart figures were "very close," and that she would **not** be microcephalic by some accepted measures. This latter point is conclusive. It is fatal to the special master's statistical analysis. Moreover, "microcephaly" is not a disease entity, it has no natural course, and Dr. Evans stated that most cases are worse than the instant one. Seizures are not a classic or stereotypical symptom. Nor is cerebral palsy.

The inappropriate and illogical stretch of the facts to find a "preexisting condition" is the essence of the error in the Office of Special Masters of the United States Court of Federal Claims. There was no preexisting condition, certainly not such an entity as is contemplated by the express language and legislative intent of the Vaccine Act. A preexisting condition under the Act must be an "illness," a "disability," an **already manifest** lack of good health. Under the Vaccine Act, to significantly aggravate

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[3] Prior to the recent report referenced in footnote 1, *supra*, the Secretary insisted that there was no solid scientific evidence to indicate that DPT could cause permanent injury.

a "preexisting condition" there must be **greater** disability, pain or illness[4] (emphasis added). There can not be "greater" illness unless there is **already** illness.

The "organic brain syndrome" – ***and*** the "microcephaly" which the government asserted as its distinguishing feature – is HYPOTHETICAL. As a result, the plain language of the Vaccine Act[5] prohibits reliance upon such a "factor unrelated." Indeed, the new feature of the rule below – an emminently correct rule – is that the Court of Appeals has finally recognized and enforced the clear and explicit statutory limitations upon the affirmative defense of "factors unrelated to the administration of vaccines."

The government would have the courts in this case to ignore the substantial difference between "borderline microcephaly" and the full-blown, overt condition. True, clinically significant microcephaly signals a complete lack of brain growth and development. But "borderline microcephlaly" is a condition which is not incompatible with normal growth and development, and all evidence indicates that Maggie Whitecotton was normal at the time of the shot which did her in.[6] In short, the government's case syllogism throughout herein has been essentially the absurd proposition that the child with a small head, small

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[4] 42 U.S.C. § 300aa-33(4).

[5] The text of 42 U.S.C. § 300aa-13(a)(2)(A) is set forth at page 3 of Petitioner's Brief.

[6] Tests at the time of the first hospitalization for seizures indicated a demylinating process at work. This is a classic sign of vaccine injury, and of acute brain injury in general.

stature, and no other problems, is not entitled to compensation for a legally presumed vaccine injury, despite severe onset of brain injury symptoms within three days of a DPT vaccine.

The child's current treating physician testified at trial and supported the earlier, contemporanous diagnosis of a vaccine injury. Yet, the government and the special master worked, almost in concert, to defeat the claim. The egregious result below **compelled** the Federal Circuit Court of Appeals' articulation of a much-needed rule of caselaw,[7] one which does little more than to affirm the statutory presumption of causation. The only significance of the rule is that in doing so it overrules a long line of bad precedents and rules of decision in conflict with the express statutory language.

ADDITIONAL STATUTORY PROVISIONS INVOLVED

The pivotal statutes which illustrate that the Court of Appeals decision is correct are principally found in the "Qualifications and Aids to Interpretation" to the Vaccine Injury Table set forth in 42 U.S.C. § 300aa-14(a)[8]

The pertinent provisions of the statute are the various definitions of "encephalopathy," and the provisions

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[7] The typical review of vaccine cases is **exceedingly** deferential to the Office of Special Masters. *See, e.g., Phillips v. Secretary of DHHS*, 988 F.2d 111 (Fed. Cir. 1993).

[8] The Table is partially set forth at pages 3-4 of Petitioner's Brief.

of the statute (found at 42 U.S.C. § 300aa-13(a)(2)) reproduced in Petitioner's Brief, relating to the "factors unrelated."

The Petitioner has quoted that part of 42 U.S.C. § 300aa-14(3)(A) which defines "encephalopathy" as "any significant acquired . . . impairment of function of the brain." (Petitioner's Brief at page 4). Significant language also from that subsection states that "Among the frequent manifestations of encephalopathy are focal and diffuse nuerologic signs, increased intercranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions."

The provisions of 42 U.S.C. § 300aa-14(b)(4) state in pertinent part:

> "For purposes of paragraphs (2)[9] and (3), the terms "seizure" and "convulsion" include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs."

It is the obvious import of 42 U.S.C. § 300aa-14(b)(3)(B) read together with sections 14(b)(3)(A) and 14(b)(4), that "encephalopathy" embraces seizures, and is conclusively shown by seizure activity.

The statute also creates a particular subspecies of encephalopathy, known as the "residual seizure disorder." The statute provides at 42 U.S.C. § 300aa-14(b)(2):

> "A petitioner may be considered to have suffered a residual seizure disorder if the petitioner ***did not suffer a seizure*** or convulsion . . . ***before***

[9] Subparagraph (2) relates to and defines "residual seizure disorder."

> ***the first seizure*** or convulsion ***after*** the administration of ***the vaccine*** involved ***and if*** . . .
>
> (B) . . . ***the first seizure occurred within three days*** after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine . . . "
> (Emphasis added.)

The four categories of possible factors unrelated in the "General Rule," 42 U.S.C. § 300aa-13(a)(2), are repeated at 42 U.S.C. § 300aa-14(b)(3)(B), which states: "The following qualifications and aids to interpretation ***shall apply to the Vaccine Injury Table*** in subsection (a)" (emphasis added).

The statute plainly sets forth the restriction, in "Table" cases, to these four classes of alternate cause:

> " * * * (3)(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy ***was caused by*** infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. ***If*** at the time a judgment is entered on a petition filed under section 2111 for a vaccine-related injury or death ***it is not possible to determine the cause***, by a preponderance of the evidence, of an encephalopathy, ***the encephalopathy shall be considered to be a condition set forth in the table*** . . . "
> (emphasis added)

MISSTATEMENTS OF FACT WHICH BEAR UPON THE PETITION

Maggie Whitecotton cannot be said to have been born with, or to have acquired prior to her third DPT shot, "a condition known as microcephaly." (Petitioner's brief at 6.) While the defense asserts she was in the second percentile of head size at birth (Appendix B at 11a, Petitioner's Brief), she was not.[10] Even if accepted as true, this state of head growth does not constitute a "condition" as contemplated by the Vaccine Act. Nor does it support the findings of the special master. As noted by the Court of Federal Claims (Petitioner's Brief Appendix B at page 21a, fn 5): "she was microcephalic prior to the vaccination ***unless the most narrow definition, three standard deviations from the mean, were adopted.***"

The government implies throughout that Maggie Whitecotton did not "get markedly worse" (*see, e.g.*, the discussion at 14-15, Petitioner's Brief) after her third DPT shot. But in fact, "Maggie was healthy, developmentally and physically, until she received her third diphtheria-pertussis tetanus (DPT) vaccination . . . " (Decision of the Federal Circuit, Appendix A page 2a, Petitioner's Brief.) Today, Maggie is non-verbal, she has cerebral palsy, and is moderately mentally retarded. Her health most clearly deteriorated after her third shot. Her school-age booster shot induced a coma within twelve hours.

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[10] Two "standard deviations" below normal is at the mid-point between the 2nd and 3rd percentile. The government has consistently confused "2 SD" with "2nd percentile."

SUMMARY OF ARGUMENT

Quite plainly, there is no logic to the special master's initial denial of compensation (**even if** "ideopathic" conditions were fair game for "factors unrelated"). The logic would **always** be defective unless the so-called "most narrow" definition of "microcephaly" were used, **and** if the child's condition fit the full-blown microcephaly of that "most narrow"[11] category, *i.e.*, headsize smaller than three SD below the mean. The broader, loose definition of two SD from the mean is translatable into nothing more (nor more ominous) than "small head."

The "onset" of a condition under the Vaccine Act is the key to the Table presumption. The special master found that Maggie Whitecotton qualified for treatment under the concept of "residual seizure disorder." (Appendix C, Petitioner's Brief, page 27a.) But at any rate the case is a proper case for an award of the necessary compensation to emeliorate the consequences of an enduring encephalopathy.

The government postulates **absurd** consequences if the rule below is allowed to stand. The government begs this Court to restore the "integrity" of the Vaccine Program. In point of fact the rule below **brings** to the Program a much-needed integrity.

The government would have the courts to ignore the fact that the Vaccine Act is a compensation statute, one

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[11] As it will appear, what Judge Turner termed the "most narrow" definition (which is more than 3 SD below the mean) is the only type of "microcephaly" with clinical significance to "inevitable" mental retardation.

with policy implications and objectives. The express intent of the Act is to dispense with close questions of causation. Yet no case could be closer than the instant case to an **actual** DPT injury. Moreover, the Act is intended to promote confidence in the mandatory immunization program via generous compensation of **apparent** vaccine injuries. The conclusion is obvious that the *Whitecotton* rule is mainstream compensation doctrine. It means nothing more nor less than that the express statutory language is to be honored. It is a long-overdue case which gives life to the heretofore ignored statutory presumption of injury by vaccine, injury "***associated with***[12] one . . . of the vaccines set forth in the Vaccine Injury Table."

It is undisputable that the special master in this case extrapolated the small head size (**standing alone**) of Maggie Whitecotton beyond the parameters of the medical testimony and the literature. The special master formulated his own impossible-to-defend medical opinion and prognosis. And thus, while the child actually had a head size prior to her encephalopathy (which occured in "table time" after the DPT shot, under the Vaccine Injury Table) which was between the second and third percentile of the population, the special master assigned her a prognosis of "90% inevitable" severe disability. The population itself puts the lie to this. It is impossible to sustain the notion that ninety per cent of the persons in the general

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[12] This is the liberal definition of "vaccine-related injury" from 42 U.S.C. § 300aa-33(5) (emphasis added).

population with like head size to Maggie have such disability characteristics. And if the extrapolation of statistics were true, the population of mentally-retarded people – ninety percent of the people with small heads – would be enormous.

Finally, there is little substance to the argument that the *Whitecotton* case deserves *certiorari*. The case is an early case in the evolution of a new system. The fiscal concerns voiced are completely artificial. That is, the Act is a legal replacement for other government programs which **could** provide substantially the same benefits as are paid in "retrospective" cases to any disabled person whose guardian has the legal grasp and fortitude to seek these benefits from myriad agencies. The "prospective" cases under the Act are funded from a Trust Fund which is flush with monies generated by a tax on vaccines.

There is no conflict between the decision of the Federal Circuit and the mainstream of compensation law. Nor is there a misapplication of the statute itself. The government is simply piqued at the prospect of no longer having its way with vaccine-injured petitioners.

The government's desire to relitigate is in no wise a justification for the exercise of the supervisory jurisdiction of this Court. The clarification of the *Whitecotton* rule should take place in the trial forum, the traditional crucible of contested cases which provides the heat and fire in which the law is traditionally forged.

STATEMENT OF REASONS FOR DENIAL OF CERTIORARI

I. THE PETITION INCORRECTLY REPRESENTS THE FACTS AND LAW WHICH COMPELLED A FINDING bELOW IN FAVOR OF VACCINE INJURY COMPENSATION FOR THE BENEFIT OF MAGGIE WHITECOTTON

A. Maggie Whitecotton's So-Called State of "Microcephaly" Prior to the Shot Has No Medical Significance

Congress made the statement in the original legislative history that a condition of **ongoing** seizures "might legitimately be described as preexisting." House Rep. No. 99-908, 99th Cong., 2nd Sess. page 15, *reprinted*, 6 USCCAN 6344, 6356 (1986). Coupled with the characterization of preexisting conditions as "***events*** in the person's past medical history" (*Ibid.*, emphasis added), it is obvious that Congress was not speaking of mere potentialities. The focus of the Act is on **symptoms**.

The Special Master in this case equated a questionable, borderline microcephaly with a major, full-blown disorder. The special master ignored a marked discontinuity of development **and** head growth, post-vaccination. Special Master Baird's logic allowed him to depend **entirely**[13] upon the alleged "microcephaly" to

[13] Because the special master's ultimate reasoning rested completely on the headsize, the Federal Circuit did not have to address the showing made in a Rule 60(b) motion. This showing completely refuted the special master's findings of swallowing problems, as does the medical record taken as a whole. The

determine the presence of the "chronic organic brain syndrome." Special Master Baird's finding that the mental retardation was "inevitable" is purely a matter of his own statistical analysis of head size as the proof of the defense.

The special master's conclusion and reasoning was set forth in the Decision as follows:

> "The fact that there was little evidence of complications of microcephaly prior to August 18, 1975, does not mean that Maggie would have developed normally. It is not unusual that a neurological problem does not become evident until the central nervous system of an infant or child matures to the point where developmental milestones are missed or delayed. Hypertonicity generally develops gradually. Ellen Louise Kitts, M.D., testified on behalf of the petitioners. She acknowledged that cerebral palsy typically becomes evident between six months and one year of age. Mental retardation may not become evident until much later. ***Based on her microcephaly alone, the court is able to predict with a high degree of certainty that Maggie would have been mentally retarded*** even if the DPT vaccine had not been administered to her on August 18, 1975. Dr. Menkes states in his textbook that nearly 100% of microcephalic children are mentally retarded.[14] Dr. Fenichel states that

60(b) showing – as well as the pictures in evidence and the testimony of the current treating physician, a physiatrist – similarly refutes the idea that cerebral palsy or hip subluxations existed prior to the shot and its concomitant brain injury.

[14] Dr. Menkes' textbook is speaking of clinically categorized children, with headsize more than 3 SD below the mean.

"almost every individual with microcephaly is mentally retarded." Dr. Evans testified that only

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But there is no disputing that Maggie's headsize was on the borderline of **two** standard deviations below the mean, up until several months **after** the shot. The majority of authorities would see this as of little significance:

> "The word microcephaly is sometimes loosely used for a head which looks small, but is perhaps better restricted to patients with a maximal occipitofrontal head circumference ***smaller than three standard deviations below the mean*** for their age and sex." Brimblecome, Children in Health and Disease, page 489 (emphasis added).

See also Kemp, Current Pediatric Diagnosis and Treatment, Ninth ed., chapter 23, page 692 (defining microcephaly as "a head circumference three SD or more below mean for age and sex"); Rudolph, editor, Pediatrics, 17th ed., page 402 ("Most investigators have defined microcephaly as a occipital-frontal circumference (OFC) of less than three standard deviations (SD) below the mean for age and sex."); Pediatric Neurology, 3rd ed., Harper and Row, page 71 ("For standardization microcephaly is arbitrarily defined by a cranial circumference less than three standard deviations below the normal for age and sex."); Wasserman, Survey of Clinical Pediatrics, 7th ed., page 346 ("Microcephaly . . . the head circumference is always three standard deviations below the mean"); Signs and Symptoms in Pediatrics, Lippencott, Chapter 22, page 112 ("There is some disagreement about the clinical definition of microcephaly. The criterion of head circumference more than two standard deviations . . . has been used; measurements three or more standard deviations below the mean have also been recommended."); Differential Diagnosis in Pediatric Neurology, Lagos, page 209 ("Arbitrarily, true microcephaly is defined as a head circumference of minus three or less standard deviations below the mean for a certain age."); Green, Pediatric Diagnosis, 3rd ed., ("Microcephaly is the term applied when the head circumference is two or three standard deviations below the mean for age, sex, height and weight."); and Dorman, Developmental Medicine and Child Neurology, 1991, page 267, ("Microcephaly

> about 7.5% of microcephalics have normal intelligence. Thus, ***there was a greater than 90% likelihood that Maggie would have been mentally retarded based on her microcephaly alone.***" (Special Master's Decision, Petitioner's Brief, Appendix C, pages 37-38a)

The conclusion made by Special Master Baird (that 90% of "microcephalics" are mentally retarded) is proven wrong by a comparison between the actual number of people who are classified as mentally retarded, with the actual number of "microcephalic" people who **would** be mentally retarded under the loose definition adopted by the special master.

Statiticians use the *standard deviation frequency curve* to show how all head sizes vary from the average or "mean" size. The more the head size varies from "average normal," the higher the number that is used to define the deviation. The curve bases its variations on set percentages from the average, and the "Standard Deviations" (SD) begin at either +1 or -1, and continue in both the positive and negative directions until they reach 4 or 5 SD.

The *standard deviation frequency curve* always places 2½% of the total below the "-2 SD" point, which would be 25 people per 1000 population. *See*, Friedman, et al., Statistics, 2nd ed., Chapter 5, "Growth Charts," pp. 74-76, (W. W. Norton Co., 1991).

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has been variously defined as a head circumference more than two SD or more than three SD below the mean.").

All the major texts, government agencies, and private organizations recognize that three percent of the population of the United States may be classified as mentally retarded. The Special Olympics movement publishes a chart entitled "Brief Facts on Mental Retardation", utilizing data from the Association for Retarded Citizens. It begins[15] as follows:

BRIEF FACTS ON MENTAL RETARDATION

250 million persons (approximately) in the United States.

7.5 million persons with mental retardation in the United States.

100,000 babies are born in the United States each year with mental retardation.

The chart ends[16] with a statement of the distribution of mental retardation by age and severity (the proportions would not have changed), using 1980 figures:

ESTIMATES OF RETARDATION BY AGE AND DEGREE

1980 Estimate	**All Ages**	**Under 21**	**Over 21**
General Population	220 mil.	85.8 mil.	134.2 mil.
3% General Population	6.6 mil.	2.6 mil.	4.0 mil.

[15] The entire chart was reproduced for the Federal Circuit.

[16] The chart also regards retardation as a separate entity, and states *inter alia* that "In the United States, mental retardation is . . . 9 times more prevalent than cerebral palsy."

Mental Retardation Levels

Profound (IQ under 20) approx. 1½%	99 thou.	39 thou.	60 thou.
Severe (IQ 21-35) approx. 3½%	231 thou.	90 thou.	141 thou.
Moderate (IQ 36-50) approx. 6%	396 thou.	154 thou.	242 thous.
Mild (IQ 51-70) approx. 89%	5.9 mil.	2.3 mil.	3.6 mil.

Reference-Association of Retarded Citizens – 1988

Special Master Baird stated in essence that "90% of all microcephalics are mentally retarded." He clearly made this statement after adopting the most broad definition of microcephaly (everyone below **-2 SD – 2½ per cent of the entire population**). What his holding means is that 22.5 people out of any group of 1,000 (90% of 25 = 22.5) are not only microcephalic, but mentally retarded as well. There is no sustaining this dramatic statement. The Special Olympics chart reveals that only 3% of our nation's population (30 individuals out of every group of 1000 people) are to be classified as mentally retarded, and this includes the vast majority who are only mildly mentally retarded. The special master must believe (by virtue of his erroneous statements) that 22.5 of every 30 of these individuals have small heads. This is ridiculous. The vast majority of the mentally retarded are physically normal and **they do not have small heads**. In order to render Special Master Baird's strong statement factual, one

would have to relate it to individuals with head size that falls into the -3 SD or even the -4 SD group. **Absolutely nothing can be assumed to be wrong with the people with non-visibly detectable smaller heads – such as Maggie's – who only border on the -2 SD group**. Most of the statistics concerning microcephaly have been compiled from clinical records involving only those who are ailing, and not from the entire spectrum of microcephalics. As shown by literature on the record,[17] those that were tested in normal life (in the public schools) showed no signs of below average intelligence, and some were even superior. It is only logical that people who are living a normal life would not be tested for retardation, even if is discovered that their heads measure a certain, statistically small size.

The Sells study notes a paucity of research regarding microcephaly in normal populations, and cites Nelson and Duetschberger (Dev. Med. Child Nuerol. 12:487, 1970) as a source of a 50% risk figure. The conclusion is obvious: Maggie Whitecotton had at least as much chance to be normal as she had to be disabled.

Therefore it was, and is, absurd to assign any credibility at all to the statistical game playing below. The vast majority of mentally retarded people are physically normal, and they don't have small heads. The DPT shot would appear to any layman, as it appeared to the diagnosing physicians, to be the culprit in Maggie's disability.

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[17] Sells, *"Microcephaly in a Normal School Population,"* Pediatrics, Vol. 59, No. 2 (February 1977)

Maggie Whitecotton is the type of child for whom the Vaccine Act was written. Even if a petitioner has an increased likelihood of injury, the proverbial "egg shell skull,"[18] there is no legal significance in that fact:

> "While it is true that some children, because of their physical condition, are more likely to react to a vaccine, vaccine reactions are not completely foreseeable. . . . And since State law requires that all children be immunized before entering school, most parents have no choice but to risk the chance – small as that may be – that their child may be injured from a vaccine." H.R. 99-908, page 6, *reprinted*, 6 USCCAN 6344, 6347 (1986).

B. There Is No Defense to a Table Claim Except in the Enumerated Alternate Causes

The presumption created by the Table is given sway in the Act over **any** "factor unrelated" **except** the listed four. That is, if there is a Table Case, the factor unrelated must be clearly shown as the result of "toxins, trauma, infection or metabolic disturbance." Even then, there is only a "factor unrelated" in the absence of a contributory role for the vaccine. The statute is explicit in stating that a "Table" condition is to be found ("the encephalopathy

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[18] The unmistakable tone of the Petitioner's Brief is that previously compromised children are **immune** from vaccine injury.

shall[19] ***be considered to be a condition set forth in the table***") if it is not possible to determine by a preponderance of evidence whether the permanent encephalopathy results from the Table Time reaction or from the restricted list of factors unrelated. 42 U.S.C. § 300aa-14(b)(3)(B) (emphasis added).

The contrast between Sections 300aa-13 and 300aa-14 illustrates the point that an inborn condition is **irrelevant** in a Table Case (unless it is, by coincidence, the result of a **known** trauma, or the cause of a "metabolic disturbance"). To find this contrast, the court must compare the operative language which creates the two-step inquiries in these two sections.

The two-step inquiry for § 13 purposes is general, mandating first that the petitioner show "the matters required in the petition." Then, the determination is made that there is no proof of cause by factors unrelated. 42 U.S.C. § 300aa-13(a)(1)(A) and (B). It is necessary to focus on the modifier in subsection (2), to-wit: "***for the purposes*** of paragraph (1)," in contrasting the operative, modifying words, respectively in subsections (2)(A) and

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[19] The mandatory word "shall" in this subsection creates an ambiguity when it is contrasted with the language of its neighboring clause, 42 U.S.C. § 300aa-14(b)(2)(B), to-wit:

> "A petitioner ***may*** be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure . . . before the first seizure . . . after the administration of the vaccine . . . " (Emphasis added.)

Judge Turner of the Court of Federal Claims relied on this wording to rule that this provision does not **require** a finding of residual seizure disorder, **even if** its conditions are met. The Federal Circuit quite properly overruled this holding.

(2)(B). These modifiers are, to-wit: "(factors unrelated) ***does not*** include" and "(factors unrelated) ***may*** include."

Thus, speaking of "factors unrelated" for the **general** purposes of the two-step inquiry under Section 13, the statute says what factors unrelated are **not** ("does not include" . . . etc.), but it does not say completely what they **are**. They only **include** toxins, trauma, metabolic disturbance, and infection. Thus, they may arguably include genetic disorders, or "chronic organic brain syndrome." However, as in the case of any of these listed processes, it is impossible to prove actual causation without describing a mechanism for injury **at the specific time and place**. According to the actual causation case law, this is what must be shown. *See, e.g., Grant v. Secretary of DHHS*, 956 F.2d 1144 (Fed. Cir. 1992).

In contrast, the operative language in Section 14 shows that the **Table** Injury does **not** allow consideration of the open-ended definition of "factors unrelated." Instead, the language denotes **exactly** what it takes to rebut the presumption of vaccine-related causation. The language states that a condition either "***shall*** be considered a condition set forth on the Table," or that it "***shall not be*** considered a condition set forth on the Table." (Emphasis added). In this latter case, the showing to rebut the presumption is not open-ended:

> "If . . . an encephalopathy ***was caused by*** infections, toxins, trauma ***or*** metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table . . . " 42 U.S.C. § 300aa-14(b)(3)(B) (emphasis added).

The resolution of the ambiguity between permissive and mandatory language in the qualifications and aids to interpretation must be accomplished in a manner consistent with the overall purpose of the act. *See, Director Office of Worker's Compensation Programs, U.S. Department of Labor v. Perini North River Associates*, 459 U.S. 297, 103 S.Ct. 634, 74 L.Ed.2d 465 (1983). In the *Pereni* case, Justice Sandra Day O'Connor, writing for this Court, observed *inter alia* that it has been "long held" that the compensation statute is to be liberally construed, "in conformance with its purpose, and in a way which avoids harsh and incongruous results." *Id.*, 101 S.Ct. at 646.

> "***The system is intended*** to be expeditious and fair. It is also intended ***to compensate*** persons with recognized vaccine injuries ***without*** requiring the ***difficult individual determinations of causation*** . . . " H.R. 99-908, 99th Cong., 2nd Session, pt. 1, page 12, *reprinted* 6 USCCAN 6344, 6353 (1986) (emphasis added).

II. THE GOVERNMENT CANNOT JUSTIFY A GRANT OF *CERTIORARI* AS A MATTER OF THE RESULT BELOW AND ITS IMPLICATIONS FOR OTHER CASES.

Perhaps the most absurd of all statements in the Petitioner's Brief is the discussion beginning at page 11 which asserts that **any** seizures in the Table time of three days would result in an irrebuttable presumption in favor of compensation. It is hard to conceive how a special master could make such a decision. The legislative intent makes the following statement, with which all the special masters are doubtless familiar:

> " * * * The Committee has included significant aggravation in the Table in order not to exclude serious cases of illness because of possible minor events in the person's past medical history. This provision does not include compensation for conditions which might be legitimately described as preexisting, (*e.g.*, a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (*e.g.*, a child with monthly seizures who, after vaccination, has seizures on a daily basis). The Committee also intends that the time periods set forth in the Table apply to the significant aggravation . . . " House Rep. No. 99-908, 99th Cong., 2nd Sess. page 15, *reprinted*, 6 USCCAN 6344, 6356 (1986).

Moreover, the Court of Federal Claims has ruled in the case of children with Tuberous Sclerosis (a **potentially** but not necessarily devasating congenital disorder) that

> "The court need not tarry to conclude that a ***seemingly normal child*** who has never seized, but who suffers a latent pre-existing condition that is awakened by the vaccine also falls well within the intent of Congress to compensate under the Act." *Costa v. Secretary of DHHS*, 26 Cl. Ct. 866, 870 (1992) (emphasis added).

It would not be necessary, then, that this Court step in to prevent the type of scenario envisioned by the government as a result of the *Whitecotton* rule. It is proper that it be left standing to reinforce the essential nature of the Act:

> " * * * Congress has clearly and repeatedly indicated that it meant to provide compensation

even in those cases where there is a debatable causal link between the injury and the vaccine in question so as to ensure that those with meritorious claims would receive compensation. It was for this precise reason that Congress, in its wisdom, decided to permit recovery on a theory of presumed causation under the vaccine injury table, and has twice stated that it intended to create a system that provides compensation to persons with vaccine related injuries quickly, easily, and with certainty and generosity, and to compensate persons with recognized vaccine injuries without requiring the difficult individual determinations of causation of injury." *McClendon v. Secretary of DHHS*, 24 Cl. Ct. 329, 334 (1991).

That Congress intended Maggie Whitecotton to receive compensation is reinforced by its specific statement of legislative intent:

> "The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related. The Committee anticipates that the research on vaccine injury and vaccine safety now ongoing and mandated by this legislation will soon provide more definitive information . . . Until such time, however, ***the Committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the Table*** and whose injuries cannot be demonstrated to be caused by other factors. (emphasis added) H.R. 99-908, page 18, *reprinted*, 6 USCCAN 6344, 6359 (1986).

Prior to *Whitecotton*, the government has regarded its burden in vaccine cases as merely to **identify** the existence of a factor unrelated. And the Office of Special Masters has been far too willing to go along.

The greatest frustration of the original purpose of the Vaccine Act has been its failure to bolster confidence in the Federal government's assumption of control over the immunization effort. The overly-broad application of "factors unrelated" is a prime source of this failure. The development of judicial doctrines that require the significantly-aggravated condition to be shown as a actual injury, **by petitioners**, is the engine of this untoward trend. But the statute as conceived and written should control.

CONCLUSION

As stated before, the fiscal worries raised by the government are insubstantial. Just as an award under the Act would make the petitioner ineligible for Medicaid, the disability will only cost the taxpayers that amount of money one time, whether the benefits come from the Program[20] or from Medicaid and other agencies. And the

[20] The injustice to Maggie Whitecotton which would flow from a grant of *certiorari* are substantial. Benefits are not payable in the "retrospective" case until the date of judgment. Under 42

"prospective" injury trust fund will not run out of money. Most importantly, awards to such obviously vaccine-injured children bolster public confidence in the Program, which after all has the goal of promoting widespread immunization.

The government has completely failed to point out any substantial legal consideration as contemplated by Rule 10. There is no departure from the normal and accepted course of judicial proceedings. There is, as noted by the government (Petitioner's Brief, page 10), a consistency between the decision below and the Federal Circuit's previous decision in *Koston v. Secretary of DHHS*, 974 F.2d 157 (Fed. Cir. 1992). The matter does not present a Federal question which should be decided by this Court.

Moreover, the Program will work much more smoothly, if the government is forcefully repelled it its efforts to use the slightest excuse, the most hypothetical "factor unrelated," as a defense. Maggie Whitecotton's case was filed in 1990. The ferociously adversarial litigation has gone on too long, and consumed too many resources.

U.S.C. § 300aa-15(a)(1)(A), the benefits are "(a)ctual unreimbursable expenses from the date of judgment awarding such expenses and reasonable projected unreimbursable expenses . . . "

Whitecotton v. Secretary of DHHS should stand, as the Federal Circuit precedent which finally makes the Vaccine Act work.

Respectfully submitted this 30th day of September, 1994.

Respectfully submitted,

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